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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,645	WELCH ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2005 has been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, October 17, 2005, is attached to the instant Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-19 and 21-23 a under 35 U.S.C. 112, first paragraph enablement **is withdrawn** in view of applicants arguments and the Reichl et al. article.

The rejection of claims 1-19 and 21-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of applicants arguments and the Reichl et al. article.

Claim Rejections - 35 USC § 102

The rejection of claims 1-19, 21 and 22 under 35 U.S.C. 102(e) as being anticipated by Morgenthaler et al. (U.S. Pat. No. 6,407,212) **is withdrawn** not because of applicants arguments

but because upon review the reference is found not to be a proper 102 (e) reference. In this instance the reference of Morgenthaler et al. is a US patent of an international application that was filed before November 29, 2000.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 7-19, 21-23 and newly added claims 24-27 under 35 U.S.C. 103(a) as being unpatentable over Nebe (WO 96/05846, IDS Paper No. 1), Omar et al. (U.S. Pat. No. 5,696,236, IDS Paper No. 1) and Savage et al. (EP 0 798 003 A2, IDS Paper No. 1) **is maintained** for reasons of record.

The rejection of claims 2-6 which apply to the references of Omar et al. and Savage et al. **is withdrawn** in view of applicants' arguments and the enablement rejection set out below.

Applicants' arguments have been fully considered but fail to persuade. Applicants' argument is that the instant claims require that there is "no detectable prion protein in the filtrate after filtration." This argument is not persuasive because the dependent claims (claim 21 and 22) only require that the removal must be at least 10^3 or 10^4, this limitation is imputed onto claim 1 which is suppose to be broader than the dependent claim.

Nebe (WO 96/05846, IDS Paper No. 1) teaches the removal of prion form solution utilizing a series of membrane or ultramembrane filters. The method teaches using a prefilter of nylon gauze and nylon membrane filers ranging in size from 2 microns to 0.2 microns (see page 10). The filters can be arranged in a series. The reference indicated that prion particles can be removed from the liquid and as an additional benefit at the same time other infectious martial can be removed such as bacteria, viruses and endotoxins (page 6). The reference also teaches that

the prefilter alone removed half of the infectious agent (see page 13), indicating that the prion agent has a high binding affinity for the prefilter material. The reference also teaches that after the first ultra filtration alone the reduction in the prion protein was by a factor of $10^{4.67}$. The reference teaches that through the use a ultrafiltraion the prion titer can be reduced even further, the process can be set up as series of filtration steps with each step further removing more of the infections prion.

Omar et al. teaches separating virus from protein solution using an absorbent (binder) that is either diatomaceous earth, perlite or kieselguhr (see claims). The method purifies a human blood plasma solution for the purpose of producing safe blood products (column 1, lines 10-30).

Savage et al. teach a method of removal of viruses from an aqueous liquid containing proteins, the method comprises the steps of passing the liquid though a depth filter formed of matrix comprising porous elements having a size 0.25 –2 microns.

It would have been obvious to one of ordinary skill in the art to utilize a depth filter, which are ordinarily used in the art as a prefilter for ultramembrane filtration (Savage et al. page 2, lines 47-48). The removal of prion particles from a liquid can be achieved based on the teaching of Nebe which indicated that half of the infectious prion was removed using the nylon premembrane filter (depth filter) indicating that the prion has a high nonspecific affinity for the prefiltration media. The claims as written are not limited to the use of only one type of filter the method steps "comprise" the use of a depth filter, which is known in the art to be a prefilter, the claims can include other filtration steps to achieve the purpose of removing the prion protein from the sample. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional,

unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

The claims are rejected as being obvious over Nebe et al.

New Rejections:

Claims 1, 8, 9, 14, 16, 17, 18, 21, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nebe (WO 96/05846, IDS Paper No. 1).

The instant invention is dranw to a method comprising the use of a depth filter (a prefilter) for the purpose of removing infectious prion protein from a solution. The claims as written are not limited to the use of only one type of filter the method steps "comprise" the use of a depth filter, which is known in the art to be a prefilter, the claims can include other filtration steps to achieve the purpose of removing the prion protein from the sample. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351,

1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG Industries v. Guardian Industries*, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Nebe (WO 96/05846, IDS Paper No. 1) disclsoe the removal of prion form solution utilizing a series of membrane or ultramembrane filters. The method teaches using a prefilter of nylon gauze and nylon membrane filers ranging in size from 2 microns to 0.2 microns (see page 10). The filters can be arranged in a series. The reference indicated that prion particles can be removed from the liquid and as an additional benefit at the same time other infectious martial can be removed such as bacteria, viruses and endotoxins (page 6). The reference also teaches that the prefilter alone removed half of the infectious agent (see page 13), indicating that the prion agent has a high binding affinity for the prefilter material. The reference also teaches that after the first ultra filtration alone the reduction in the prion protein was by a factor of $10^{4.67}$. The reference discloses that through the use a ultrafiltration the prion titer can be reduced even further, the process can be set up as series of filtration steps with each step further removing more of the infections prion protein. Nebe anticipates the instant invention.

Claims 1-19, 21-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for KS80 depth filter, does not reasonably provide enablement for the use of any depth filter under any condition to remove prion protein from a sample source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicants have shown that the KS80 filter which is made up of cellulose kieselguhr and perlite is able to remove prion protein form a samples source. The reference cited by applicants Reichel et al. (Vox Sanguinis, 2002, submitted in IDS of October 17, 2005) indicates that the instant invention of removing prion protein from the sample works with the KS80 filter only when there is ethanol in the sample. The experiments in the Reichel et al. reference follow the Cohn fractionation process. Cohn fractionations is routinely is used for the purification of Ig or albumin form a serum sample. The purification process utilizes mixing the serum sample with cold ethanol. At varying concentration of ethanol the proteins form a precipitate which can then be removed by centrifugation producing a precipitate and a supernatant fraction. These supernatant fractions were tested using different depth filters. The AP20 filter, a borosilicate microfiber filter, was not able to remove the prion protein from the sample (see table 1, in Reichel et al.), because sample A5 and B2 produced infection in an inoculated animal (see table 1 and 2, in Reichel et al.). The instant invention is not enabled for removing prion protein using any filter and any condition.

The presence of ethanol is required for the removal of prion protein from a sample, see Vey et al. (Biologicals, 2002, see tables 1-6). The removal of the prion protein not only depends on the depth filter used (type of filter) but also depends on the ethanol concentration in the

sample. The instantly claimed methods are not enabled for the full scope because the ability to remove the prion protein from a sample varies greatly between the depth filter and the ethanol concentration of the sample. Not all dept filters, such as the AP20 filter, are able to remove the prion protein so that the liquid is made non-infective. The instant specification does not enabled the invention for the claimed scope.

Claim Objections

Claims 1, 21, 22 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicants in their arguments have indicated that claim 1 requires "no detectable prion protein in the filtrate after filtration" while claims 21 or 22 would allow detectable prion in the sample. Thus claims 21, 22 and 24 are broader than the claim from which they depend and they thereby fail to further limit claim 1.

Conclusion

Claims 1-19 and 21-27 are rejected.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER
1/9/06